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EXAMINER

GOTTSCHALK, MARTIN A

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| ART UNIT | PAPER NUMBER |
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3626

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,533

Applicant(s)

HUFFORD ET AL.

Examiner

Martin A. Gottschalk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 31-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-30 and 48-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. Claims 1-52 are pending. Claims 1-3 and 31-47 are withdrawn. Claims 4-30 and 48-52 are unamended.

Election/Restrictions

2. This application contains claims 1-3 and 31-47, drawn to inventions nonelected with traverse in Applicant's communication filed 11/07/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

3. The rejection under the second paragraph of 35 U.S.C. 112 is hereby withdrawn due to amendment.

Note: The following claims, rejected under 35 U.S.C. 102 and 103, are unamended save for claims 21-22 which were amended to cure the 35 U.S.C. second paragraph deficiencies discussed above. The claims are reprinted here for the convenience of the reader. In the previous Office Action, the statement of rejection for the Stark reference under 35 U.S.C. 102 inadvertently referred to "Claims 1-30..." as being rejected, when

in fact, claims 1-3 had been withdrawn subject to restriction election and claim 12 was rejected under 35 U.S.C. 103; thus the statement should have read, "Claims 4-11, 13-30 ..." Correction has been made below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 4-11, 13-30 and 48-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Stark et al (US Pat# 6,827,670, hereinafter, Stark).

A. As per claim 16, Stark discloses a method of predicting subject noncompliance, comprising the steps of:

(a) providing historical subject compliance data (Stark: col 5, ln 64 to col 6, ln 1; col 7, 57-60; col 11, lns 40-48; Fig. 11, i.e. patient compliance data from the past 10 days is provided to the central computer.);

(b) generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data (Stark: col 12, lns 48-63; Fig 14, note the graphic representation which is a type of quantitative analysis.);

(c) translating the at least one predictive algorithm into at least one prediction rule (Stark: col 13, lns 6-16. The Examiner considers that the algorithm is translated it into a rule such as, "If the patient has achieved near 100% performance, then the challenge level of the protocol should be increased".);

(d) obtaining subject compliance information (Stark: col 11, lns 40-48; Fig. 11, i.e. compliance data is obtained from the patient; col 13, lns 2-5, reads on, "...level of average compliance.");

(e) comparing the subject compliance information to the at least one prediction rule to determine if action is needed (Stark: col 5, lns 34-36; col 13, lns 2-5); and

(f) prompting action if the step of comparing indicates that action is needed (Stark: col 13, lns 13-16, reads on "...algorithm increases the challenge level...").

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B. As per claims 4-6, 8, 14, 24, and 26, they are rejected for the same reasons as provided above for the corresponding steps of claim 16.

C. As per claim 17, Stark discloses the method of predicting subject noncompliance of claim 16,

wherein said step of providing includes

providing historical protocol data (Stark: col 5, lns 2-4; Fig 9, note that item 107 is labeled "Receive a Protocol" and is connected by arrow 108 coming from the box labeled "Historic Protocols...")

and

wherein said step of generating includes

quantitative analysis of the historical protocol data (Stark: col 7, lns 41-43).

D. As per claims 9 and 25, they are rejected for the same reasons provided above for claim 17.

E. As per claim 18, Stark discloses the method of determining subject noncompliance of claim 17, wherein the step of providing

employs at least one database containing the historical protocol data (Stark: Fig 9, item 36 and the box labeled "Historic Protocols..." which is shown to be receiving input from item 40; Fig 10, item 36).

F. As per claim 10, it is rejected for the same reasons as provided above for claim 18.

G. As per claim 19, Stark discloses the method of predicting subject noncompliance of claim 16, wherein the step of obtaining includes

the use of a portable electronic device capable of displaying information and receiving and storing input from a user (Stark: col 8, lns 12-30).

H. As per claims 7, 11, 15, and 30, they are rejected for the same reasons provided above for claim 19.

I. As per claims 20 and 21-22, Stark discloses the method of predicting subject noncompliance of claim 16 and 20 (for 21 and 22), further comprising the step of

(claim 20) creating an evaluability database adapted to store data related to subject compliance;

and

(claim 21) providing access to the evaluability database to a sponsor to allow the sponsor to make a determination regarding a subject based on data from the evaluability database;

and

(claim 22) evaluability database is tailored to a condition affecting the subject (For all three claims, Stark: col 8, Ins 57-63, whereby sponsor reads on "treatment professional", and the cited "treatment protocol" is considered to be tailored to a condition affecting the patient. See also col 7, ln 63 to col 8, ln 3).

J. As per claim 23, Stark discloses the method of determining subject noncompliance of claim 16, wherein the step of providing

employs at least one database containing the historical subject compliance data (Stark: Fig 9, item 36 and box labeled "Historic Protocols..." which is shown to be receiving input from item 40; Fig 10, item 36).

K. As per claim 13, it is rejected for the same reasons as provided above for claim 23.

L As per claims 27 and 28, Stark discloses the method of enhancing subject compliance of claim 24, wherein the affirmative action includes

(claim 27) reducing

and

(claim 28) increasing

a number of occurrences of the step of obtaining subject compliance information (For both claims, Stark: col 9, ln 67 to col 10, ln 21. The Examiner considers the "...replicate count..." to be a form of compliance information, and notes it is increased following detection that the previous "...effort or angle objective..." was not being achieved. Since the number of occurrences of a replicate would be increased, so would obtaining this particular form of compliance information. Likewise, if the patient is "...satisfying ahead of schedule, the treatment goal...", logically, the algorithm would move in the opposite direction from the previous example

and "...modify the treatment protocol..." such that the "protocol goals may be raised to more challenging levels...". In this scenario, the patient would require an increase in the required effort, and following the logic of the former example, the number of replicates required to comply with the treatment protocol would be reduced.).

M. As per claim 29, Stark discloses the method of enhancing subject compliance of claim 24, wherein the affirmative action includes giving a reward (Stark: col 10, lns 13-23, reads on "...psychological boost...").

N. As per claims 48-52, they are articles of manufacture claims which repeat the same limitations of claims 4, 8, 14, 16, and 24 respectively, the corresponding method claims, as collections of instructions for execution stored on media suitable for use in an electronic device, as opposed to a series of process steps. Since the teachings of Stark disclose the underlying process steps that constitute the method of claims 4, 8, 14, 16, and 24, it is respectfully submitted that they likewise disclose the instructions for executing the steps as well. As such, the limitations of claim 48-52 are rejected for the same reasons given above for claims 4, 8, 14, 16, and 24 respectively.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stark as applied to claim 8 above, and further in view of Smith (Smith, G., "Statistical Reasoning." Third edition. Ch. 15, pgs. 619-667. Allyn and Bacon, a Division of Simon and Schuster, Inc., Needham Heights, MA. 1991, hereinafter Smith.).

A. As per claim 12, Stark suggests the use of statistical analysis and techniques (Stark: col 7, lns 41-48) but fails to explicitly disclose the specific statistical techniques of claim 12.

However, these features are well known in the art as evidenced by the teachings of Smith who discloses the method of determining subject compliance of claim 8, wherein

the step of generating employs at least one of the group of

multiple linear regression (Smith: Ch 15.)

discriminant function analysis,

logistic regression,

neural networks,

classification trees and

regression trees.

It would have been obvious at the time of the invention to one of ordinary skill in the art to incorporate the teachings of Smith within the method of Stark with the motivation of isolating the separate effect of each of several independent variables on a single dependent variable (Smith: pg 620, second paragraph).

Response to Arguments

9. Applicant's arguments in the response filed 06/09/2006 have been fully considered but they are not persuasive.

A. On page 14 of the response Applicant argues that the features of claim 4 and 48 are not taught by the Stark reference. As per the first step of providing historical subject compliance data, Applicant argues that the cited passage does not provide *historical*

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compliance data. The Examiner respectfully disagrees. In col 7, the reference is replete with historical patient treatment information being provided to and from a database, and in particular, Ins 57-60 refer to "patient compliance information" which is used to "update the historic database" or to "allow review by a treatment professional," i.e. it is provided. Furthermore, in col 11, Ins 40-48, compliance data is collected over a 10-day period and analyzed. The Examiner considers this to be a type of historical data in that the historic period is defined by the 10 days, which are in the past.

Applicant further appears to try to distinguish between "historical subject compliance data" and "subject compliance information." The Examiner can find no definitional disclosure in the specification which clearly makes this distinction, nor has Applicant pointed to such a definition. As such, the present interpretation of the reference is considered to be sound.

Applicant also argues that the second step of claim 4 is not taught by Stark, said step reciting

generating at least one preferred compliance threshold by quantitative analysis of at least one of the group of

the historical subject compliance data

and

the historical protocol data.

The Examiner notes that in the first Office Action, the anticipatory references for claim 4 are actually provided for analogous claim 16. Note for example in the rejection of step 16 (c), the reference to col 13, lns 6-16, where it is quantitatively determined that when the algorithm-generated threshold of "performance levels near 100%" is attained, a protocol adjustment ensues. Note further in lns 30-39 that the threshold determination – i.e. "challenge levels" - incorporates past compliance data. This same analysis applies to Applicant's arguments concerning claims 8 and 49 found on pg 15 of the response. The reference passages provided above for claims 4 and 48 which correspond to "generating at least one preferred compliance threshold" apply equally to the recitation of "translating into...at least one decision rule..." in these latter claims 8 and 49.

B. On page 16, Applicant substantially applies the same arguments as the preceding to claims 14, 16, 24, and 50-52. Allusion is further made to the reference's alleged failure to disclose a "spectrum of compliance." In response, the Examiner respectfully disagrees and refers Applicant to the above comments and Stark: col 11, lns 40-48, where the Examiner considers the 10 days of historical compliance data to be a type of spectrum of compliance data, the spectrum range being the 10 days. The Examiner can find no definitional disclosure in the specification which clearly refutes this

interpretation, nor has Applicant pointed to such a disclosure. As such, the present interpretation of the reference is considered to be sound.

C. The balance of the arguments refers to dependent claims which owing solely to their dependencies from the previous claims, are alleged to not be anticipated or obvious in view of the applied references. As such, the foregoing responses to their respective independent claims apply equally to these dependent claims.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

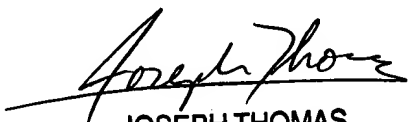
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Thurs 8:30 -6 and alternate Fri 8:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MG
08/24/2006



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SUPERVISORY PATENT EXAMINER